

**REMARKS**

The present invention relates a novel protein belonging to the TNF superfamily termed "TRANCE," nucleic acids encoding the same, and more specifically, antibodies to TRANCE.

Applicants appreciate the Examiner's time during a telephonic interview on April 5, 2005, between the Examiner, David S. Romeo, and Applicants' representatives, Quang Nguyen and Kathryn Doyle. During that interview, it was agreed that Applicants would amend the claims to recite an isolated antibody that is specific for a single form of TRANCE wherein said TRANCE either comprises or consists of SEQ ID NO:2. As such, the amendments made herein merely reflect the amendments memorialized in the Interview Summary Record, PTO Form PTOL-413, sent by the Examiner to Applicants on April 5, 2005.

Claims 10-15 and 60-66 are pending in the present application. Claims 12, 13 and 66 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 60-64 and 66 have been canceled herein without prejudice to the inclusion of the subject matter contained therein in any later filed continuation and/or divisional application(s). Claims 10 and 65 have been amended to recite an isolated antibody that is specific for a single form of TRANCE, and claims 67-71 have been added to incorporate the subject matter of claims 11-15. Support for the amendments to claims 10 and 65 is found throughout the as-filed specification as fully set forth below, and therefore, no new matter has been added by way of the present Amendment. Therefore, claims 10-15, 65 and 67-71 are pending following entry of the present Amendment.

**Amendments to the claims**

Applicants have amended claim 10 to recite an isolated antibody that is specific for a single form of TRANCE, wherein said TRANCE comprises the amino acid sequence of SEQ ID NO:2. In addition, claim 65 has been amended to recite an isolated antibody that is specific for a single form of TRANCE, wherein said TRANCE consists of the amino acid sequence of SEQ ID NO:2. The amendments to claims 10 and 65 reflect those suggested by the Examiner in the Interview Summary Record dated April 5, 2005. The Examiner has indicated that an antibody as recited in amended claims 10 and 65 is allowable because such an antibody would not be cross-reactive with any other form of TRANCE. In addition, support for these

amendments to the claims is found, as pointed out by the Examiner, on pages 45-46 of the as-filed specification, wherein it is disclosed that an antibody that is specific for a single form of TRANCE is not cross-reactive with any other form of TRANCE. Moreover, support for an isolated antibody is found throughout the specification. For example, beginning on page 46, the specification discloses various methods for producing and isolating antibodies to TRANCE. Thus, the amendments to claims 10 and 65 are amply supported by the specification as filed and therefore do not constitute new matter.

#### New Claims

New claims 67 to 71 have been added to depend from claim 65 and incorporate the subject matter of claims 11-15 with respect to claim 65. Support for these claims is identical to that for claims 11-15. As such, no new matter has been added by the addition of these claims.

#### Generic and species claims

As indicated by the Examiner on page 3 and page 4 in the Office Action dated September 10, 2004 (Paper No./Mail Date 200409), upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim (see MPEP § 809.02). In a subsequent telephone conference between the Examiner and Quang Nguyen on April 5, 2005, the Examiner agreed that the non-elected species claims directed to types of antibodies and detectable labels would now be examined. As such, Applicants understand that the Examiner has the duty to examine previously withdrawn claims 12 and 13, which depend from claim 10, and new claims 67-71, which depend from claim 65. Claims directed to a monoclonal antibody, a polyclonal antibody, and a chimeric antibody must now be examined given that independent claims 10 and 65 are deemed allowable. Further, in view of the allowance of independent claims 10 and 65, and the additional species claims imposed with respect to a detectable label, the Examiner is now obligated to examine claim 15 in its entirety and not solely to alkaline phosphatase. Thus, claim 15 should be examined with respect to alkaline phosphatase, peroxidase, and radioactive isotopes.

Response to the rejections cited in the Office Action dated December 30, 2004

Rejection of claims 10, 11, 14, 15, 60-65 pursuant to 35 U.S.C. § 101

The Examiner has rejected claims 10, 11, 14, 15 and 60-65 under 35 U.S.C. § 101 because he contends that the claimed invention encompasses an antibody as it occurs in nature and therefore is directed to non-statutory subject matter. Applicants have amended independent claims 10 and 65 to recite an "isolated antibody" thereby rendering this rejection moot.

Rejection of claims 10, 11, 14, 15 and 60-62 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 10, 11, 14, 15 and 60-62 under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting various phrases the Examiner deems indefinite. This rejection is rendered moot by the present amendments to the claims because the phrases objected to by the Examiner have been deleted.

Rejection of claims 10, 11, 14, 15 and 60-62 under 35 U.S.C. § 112, first paragraph - written description

The Examiner has rejected claims 10, 11, 14, 15 and 60-62 under 35 U.S.C. § 112, first paragraph for lacking written description. Again, this rejection is rendered moot by the present amendment to the claims.

Rejection of claims 10, 11 and 60-64 under 35 U.S.C. § 102(e)

The Examiner has rejected claims 10, 11 and 60-64 under 35 U.S.C. § 102(e) as being anticipated by Anderson (U.S. Patent No. 6,017,729). Specifically, the Examiner asserts that Anderson teaches a RANKL polypeptide which is 99.5% identically to TRANCE as set forth in SEQ ID NO:2. The amendments to the claims also render this rejection moot. As the Examiner notes in the Interview Summary Record dated April 5, 2005, Applicants' TRANCE is unique and therefore an antibody that is specific for Applicants' TRANCE is not anticipated by Anderson.

Rejection of claims 10, 14 and 15 pursuant to 35 U.S.C. § 103(a)

The Examiner has rejected claims 10, 14 and 15 pursuant to 35 U.S.C. § 103(a) as being *prima facie* obvious over Anderson in view of Kimball (1983 Intro. to Immunology. Macmillan, New York, pp 101-102). The Examiner contends that the antibodies disclosed in Anderson when combined with the methods of coupling alkaline phosphatase to antibodies for use in an ELISA, as taught by Kimball, render the present invention *prima facie* obvious. Applicants respectfully traverse the rejection.

Applicants submit that Anderson in view of Kimball cannot render claims 10, 14 and 15 *prima facie* obvious under 35 U.S.C. §103(a). Anderson does not anticipate the claims as discussed above. Similarly, Kimball does not teach an isolated antibody specifically binding to a single form of TRANCE as recited in the amend claims. Instead, Kimball merely describes methods of coupling alkaline phosphatase to antibodies as a means for generating an antibody that is detectably labeled. Thus, the teachings set forth by Kimball would not have provided any suggestion or motivation for preparing or identifying the claimed antibodies. Therefore, Anderson in view of the Kimball cannot render the present invention *prima facie* obvious under 35 U.S.C. §103(a).

Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection pursuant to 35 U.S.C. § 103(a).

Summary

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has been overcome or is now inapplicable, and that claims 10-15, 65 and 67-71 are in condition for allowance. Applicants further submit that no new matter has been added by way of the present amendment. Reconsideration and allowance of these claims is respectfully requested at the earliest possible date.

Respectfully submitted,

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(Date)

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Enclosures: Petition for extension of time